Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: 6/11/2013

2. Sponsor Identification

Guangdong Biolight Meditech Co., Ltd
Innovation First Road, Technology Innovation Coast
Zhuhai, Guangdong, 519085, China

Establishment Registration Number: 3007305624

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Position: R&D Director
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3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
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4. Proposed Device Identification

Proposed Device Name: Digital Electrocardiograph
Models: E30, E35, E40, E65, E70 and E80
Proposed Device Common Name: Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II;
Product Code: DPS;
Regulation Number: 21 CFR part 870.2340;
Review Panel: Cardiovascular;

Intended Use Statement:

Digital Electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

5. Predicate Device Identification

510(k) Number: K101876
Predicate Device Name: Digital Electrocardiographs
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

6. Device Description

Digital Electrocardiographs, E30, E35, E40, E65, E70 and E80, are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. There is ***no*** specific contraindication identified for the proposed devices.

The proposed devices acquire ECG electrical signals from patient body surface by ECG electrodes. After been amplified, filtered and transferred, the ECG signal waveforms are displayed on the LCD and recorded on the paper through thermal printer.

The components of the proposed devices, Digital Electrocardiograph, include: (1) chest electrodes (2) limb electrodes, (3) cable and (4) Batteries;

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;
- IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- AAMI / ANSI EC11:1991/(R)2007, Diagnostic electrocardiographic devices.
- ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Test for in vitro cytotoxicity;
- ISO 10993-10:2002/A2006, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity;

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	DPS	DPS
Regulation Number	870.2340	870.2340
Intended Use	Digital Electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	Digital Electrocardiographs, ECG-1210 / ECG-1230 / ECG-3010 /ECG-6010, are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.
Patient Contact Material	ABS / Cooper Alloy	ABS / Tin Alloy

Sterile	No	No
Single Use	No	No
Energy Source	AC Power / DC Power	AC Power / DC Power
Safety	IEC 60601-1 / IEC 60601-1-2	IEC 60601-1 / IEC 60601-1-2
Biocompatibility	Non-Cytotoxicity Non-Irritation Non-Sensitization	Non-Cytotoxicity Non-Irritation Non-Sensitization
Performance	AAMI EC11	AAMI EC11
Accessories	Limb Electrode Chest Electrode Battery	Limb Electrode Chest Electrode Battery

The proposed devices, Digital Electrocardiographs, E30, E35, E40, E65, E70 and E80, are determined to be Substantially Equivalent (SE) to the predicate devices, Digital Electrocardiographs, ECG-1210 / ECG-1230 / ECG-3010 /ECG-6010.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 11, 2014

Guangdong Biolight Meditech Co., Ltd.
% Diana Hong
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P.o. Box 120-119
Shanghai, 200120 CH

Re: K131858
Trade/Device Name: Digital Electrocardiograph (E30, E35, E40, E65, E70, E80)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: April 30, 2014
Received: May 5, 2014

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

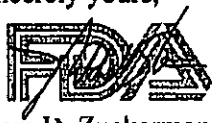
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number:
Device Name: Digital Electrocardiograph
Models: E30, E35, E40, E65, E70 and E80

Indications for Use:

Digital Electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D)	OR	☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.06.11 09:41:03 -04'00'